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Pharmaceutical with stabilised granulocytes colony stimulating factor -
contains surfactant, saccharide, protein or high mol. wt. cpd. as
stabiliser

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Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week	
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19860718; JP 86169487 A 19860718; JP 86169488 A 19860718; JP 87178031 A
19870716; JP 87178032 A 19870716; JP 87178033 A 19870716

Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
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PH 28830	A	A61K-031/715	
DE 3723781	C2	A61K-038/16	

Abstract (Basic): DE 3723781 A

A pharmaceutical contains stabilised G-CSF (granulocytes colony stimulating factor) as active ingredient and at least one surfactant, saccharide, protein or a high mol. wt. cpd. Pref. the amt. of surfactant or saccharide is 1-10000 pts. wt. Pref. pt. wt. G-CSF. Pref. the surfactant is non-ionic (esp. a sorbitan ester glycerine ester, poly-glycerine ester, polyoxyethylene sorbital ester, polyoxyethylene-glycerine ester or polyethylene glycol ester of an aliphatic acid, polyoxyethylene polyoxypropylene alkyl ether, a hardened polyoxyethylated castor oil, a polyoxyethylated bees wax deriv. a polyoxyethylene lanoline deriv. or an aliphatic polyoxyethylene acid aride), anionic (esp. an alkylsulphate or alkylsulpho succinyl ester salt) or natural (esp. lecithin, sphingophospholipid or an ester of an aliphatic acid with sucrose.

USE/ADVANTAGE - G-CSF can be used to treat various infectious diseases, but is unstable and highly sensitive to changes in the environment e.g. temp., humidity, oxygen or UV light. The invention stabilises the G-CSF and protects it completely against loss of activity.

Abstract (Equivalent): GB 2193631 B

A stable granulocyte colony stimulating factor containing pharmaceutical preparation that contains, in addition to the granulocyte colony stimulating factor present as the effective ingredient, at least one substance selected from pharmaceutically acceptable surfactants, saccharides, proteins and other high-molecular weight compounds such as natural polymers or synthetic polymers; wherein the granulocyte colony stimulating factor has the following physicochemical properties: (i) molecular weight: about 19,000 +/- 1,000 as measured by electrophoresis through a sodium dodecylsulfate-polyacrylamide gel; (ii) isoelectric point: having at least one of the three isoelectric points, pI = 5.5 +/- 0.1, pI = 5.8 +/- 0.1, and pI = 6.1 +/- 0.1; (iii) ultraviolet absorption: having a maximum absorption at 280 nm and a minimum absorption at 250 nm; (iv) amino acid sequence of the 21 residues from N terminus: H2N-Thr-Pro-Leu-Gly -Pro-Ala-Ser-Ser -Leu-Pro-Gln-Ser-Phe-Leu -Leu-Lys-Cys-Leu- Glu-Gln-Val-.

Derwent Class: A96; B04

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